DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Re: Amerge™
Docket No.: 98E-0614

APR 21 1999

The Honorable Q. Todd Dickinson
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, DC 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 4,997,841, filed by Glaxo Wellcome, Inc., under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Amerge™, the human drug product claimed by the patent.

The total length of the regulatory review period for Amerge™ is 953 days. Of this time, 519 days occurred during the testing phase and 434 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: July 5, 1995.

   FDA has verified the applicant's claim that the date the Investigational New Drug application became effective was on July 5, 1995.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: December 4, 1996.

   FDA has verified the applicant's claim that the New Drug Application (NDA) for Amerge™ (NDA 20-763) was initially submitted on December 4, 1996.

3. The date the application was approved: February 10, 1998.

   FDA has verified the applicant's claim that NDA 20-763 was approved on February 10, 1998.

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This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Thomas J. McGinnis

Thomas J. McGinnis, R.Ph.
Deputy Associate Commissioner
for Health Affairs

cc: David J. Levy, Ph.D.
GlaxoWellcome, Inc.
Five Moore Drive
Research Triangle Park, NC 27709

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

0148 '99 APR 22 P1:40

Memorandum

Date: APR 21 1999

From: Brian J. Malkin, Associate Director for Patents and Hearings
Health Assessment Policy Staff (HFY-20)

Subject: Patent Term Restoration Application
for AMERGE™

To: Dockets Management (HFA-305)

Attached is a letter to the Patent Term Office for the above mentioned human drug product under the Docket Number **98E-0614** stating that this particular patent is eligible for regulatory review. The Patent Number is **4,997,841**. Please place this recent correspondence in the appropriate file.

If you have any questions, please contact me at 827-6620. Thank you for your assistance.

DATE:

TO: Sabrina Crisp, Regulations Policy and Management Staff, HF-26

From: Brian J. Malkin, Associate Director for Patents and Hearings, HFY-20

RE: Federal Register Notice Information for AMERGE™
Docket No. 98E-0614, FRDTS# OC9948

Attached is a FR Notice for the human drug product, AMERGE™. This document has been internally reviewed and cleared by OHA.

Please note that AMERGE™ is a trademark. Therefore, the superscript "TM" notation will be needed.

Please call me if you have any questions. My number is 827-6620 (Rm. 15-22).

Thank you for your assistance.